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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,546

09/12/2006

Patrick Hanley

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IP LEGAL DEPARTMENT  
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EXAMINER

PEZZUTO, HELEN LEE

ART UNIT

PAPER NUMBER

1796

NOTIFICATION DATE

DELIVERY MODE

10/02/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,546	<b>Applicant(s)</b> HANLEY ET AL.	
	<b>Examiner</b> Helen L. Pezzuto	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-19, 21 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-19, 21 and 23-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 15-19, 21 and 23-25 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/31/09 has been entered.

***Response to Amendment***

Applicant's amendment to claims 15 and the cancellation of claim 21 filed in the response on 8/31/09 is acknowledged. Currently, claims 15-19, and 23-25 are pending in this application.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 15-19, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garnett et al. (US-511) or WO 02/48202 A1 in view of Tortorello et al. (US-361) or Takeuchi et al. (US-799).

US 6,162,511 to Garnett et al. discloses a radiation curable coating composition comprising a resin component including an unsaturated monomer, and an unsaturated oligomer/prepolymer, and binder or mixture thereof (see abstract). Suitable substrate material includes plastics such as polyolefins and metals, which fall within the scope of the instant biomedical device (col. 7, lines 63-67). Specifically, suitable unsaturated monomers include unsaturated carboxylic acid (e.g. acrylic acid), N-vinylpyrrolidone, and multifunctional acrylate within the scope of claim 2 (col. 2, lines 34-54). Prior art oligomers or prepolymers such as unsaturated polyethers, urethane, and (meth)acrylate oligomers, clearly fall within the scope

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of the instant relatively lower molecular weight polymer (col. 2, line 55 to col. 3, line 4). Suitable higher molecular weight binder polymer includes polyvinylpyrrolidone, encompassing the instant higher molecular weight polymer expressed in claim 15 (col. 3, lines 4-16). Prior art discloses molecular weight of the prepolymer and binder polymer ranges from 2,000 to 200,000, encompass those expressed in claim 15. Hydrogen abstracting photoinitiator such as benzophenone and reaction solvent were also taught to be suitably used (col. 3, lines 38-39; col. 4, lines 22-24). Prior art discloses a curing temperature ranges from ambient temperature to 150°C (col. 1, lines 47-51).

WO-202 discloses a process for producing scratch-resistant coatings comprising a photocurable formulation. Specifically, prior art process comprises preparing a photocurable formulation comprising at least one ethylenically unsaturated compound (A), a photoinitiator of formula Ia or Ib, applying the formulation to an substrate and curing the formulation by either solely irradiation with electromagnetic radiation and/or action of heat (see abstract, pages 1-2, 16). Specifically, suitable ethylenically unsaturated component (A) can be monomeric,

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oligomeric, polymeric, and mixture thereof, encompassing the instant hydrophilic monomer, and the high and low molecular weight polymers (pages 16-17, 22). WO-202 specifically teaches that the photopolymerizable compounds (A) can be used alone or in any desired mixtures, wherein mixtures of polyol(meth)acrylates are preferably used (page 20, lines 19-20). Suitable oligomer includes (meth)acrylates, urethane and polyethers. Prior art further suggest adding polymeric binder having molecular weight ranges from 5,000 to 2,000,000, and polyvinylpyrrolidone dispersant aids, defined within the scope of the instant high molecular weight polymer (pages 20-21). Suitable binder polymer includes polyethylene oxide and polycaprolactam (page 20, line 21 to page 21, line 10). Other conventional additives such as additional photoinitiators (i.e. benzophenones), and solvents are further disclosed (pages 30, 40, 42). Suitable coating substrates include polyolefins, and polyethylene terephthalate, within the scope of the instant medical device (page 38, lines 5-9). Prior art discloses a curing temperature ranges from room temperature to 150°C (page 44).

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Prior art references disclose various recited components as in the instant coating formulation, including the low and high molecular weight oligomers and polymers. To demonstrated the conventionality of using mixture of monomers, oligomers and polymers in coating compositions, ancillary references to Tortorello et al. (US-361) and Takeuchi et al. (US-799) are herein cited, wherein (meth)acrylate and urethane oligomers having the instant molecular weight is commonly used in analogous photocurable coating formulations (see US-361, col. 4, lines 39-46; US-799, col. 10, lines 24-37). Accordingly it would have been obvious to one having ordinary skill in the art to select a mixture of ethylenically unsaturated monomer, low molecular weight oligomer and high molecular weight polymer binders, a UV activable compound such as benzophenone, dispersant aids such as polyvinylpyrrolidone as needed, and an appropriate solvent to formulate a photocurable coating composition suitable for coating an implantable biomedical device as presently claimed, motivated by the reasonable expectation of success. Once the motivation to select the suitable components is provided, one having ordinary skill in the art would have readily envisage the optimum or workable proportions of the respective components to the

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suitable application, absent showing of unexpected results demonstrated for the recited ratios.

### ***Response to Arguments***

Applicant's amendment and remarks filed 8/31/09 have been fully considered. Firstly, applicant urges Garnett et al. provides a molecular weight range of 2,000-200,000 for both the prepolymer and higher molecular weight binder polymer, in contrast to those expressed in the present claim 15 which do not overlap. Applicant further urges that Garnett et al. do not provide guidance as to the ratios of prepolymer and binder polymer. The examiner is of the position that the recited molecular weights for both high and low molecular weight polymers are well within the range of 2,000-200,000 as taught in prior art. AS such, any oligomers and polymeric binders having molecular weight within the range as taught would be suitable. In any event, ancillary references to Tortorello et al. (US-361) and Takeuchi et al. (US-799) are herein cited to demonstrate the common utility of (meth)acrylate and urethane oligomers having the instant molecular weight in analogous photocurable coating formulations (see US-361, col. 4, lines 39-46; US-799, col. 10, lines 24-37). Thus, a skilled



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artisan would recognize and be able to select any oligomer/prepolymer and binder polymer within the range taught by patentees, motivated by the reasonable expectation of success. Furthermore, it would have been obvious to one having ordinary skill in the art to discover the optimum prepolymer to binder polymer ratios suitable for specific considerations and applications, within prior art general conditions. For example, US-511 teaches 50-1000 parts of urethane acrylate prepolymer based on 100 parts by weight of the resin composition in a preferred embodiment (col. 4, lines 46-54), and further disclose suitable weight ratios of monomer to the prepolymer and binder polymer suitable for specific considerations and applications (col. 3, lines 17-25). Secondly, applicant urges that WO-202 does not specifically suggest a combination of both lower molecular weight and higher molecular weight polymers, and that unsaturated component (A) can serve three separate components. The examiner respectfully disagrees. WO-202 discloses at least one unsaturated component (A) which can be monomeric, oligomeric (i.e. prepolymers) and/or polymeric (page 15, line 26 to page 17, line 20). WO-202 specifically teaches that the photopolymerizable compounds (A) can be used alone or in any desired mixtures, wherein

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mixtures of polyol(meth)acrylates are preferably used (page 20, lines 19-20). Prior art further suggest adding polymeric binder having molecular weight ranges from 5,000 to 2,000,000, which further reads on the instant high molecular weight polymer. Thus, it would have been obvious to one having ordinary skill in the art to select a mixture of ethylenically unsaturated monomer, oligomer and high molecular weight polymer binders as taught within the scope of the instant hydrophilic monomer, and high and low molecular weight polymers as taught. Accordingly, the examiner's position is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen L. Pezzuto whose telephone number is (571) 272-1108. The examiner can normally be reached on 8 AM to 4 PM, Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Helen L. Pezzuto/

Primary Examiner

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